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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,354	11/13/2000	Tetsuya Gatanaga	IRVN-007CIP2	4815

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EXAMINER

MURPHY, JOSEPH F

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 08/13/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/700,354

Applicant(s)

GATANAGA ET AL.

Examiner

Joseph F Murphy

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 57-80 is/are pending in the application.
- 4a) Of the above claim(s) 62-65, 67-71, 73, 77 and 79 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 57-61, 66, 72, 74-76, 78 and 80 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7, 8. 6) ☐ Other: \_\_\_\_\_

Art Unit: 1646

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of Group XVIII in Paper No. 12, 6/24/2002 is acknowledged. The traversal is on the ground(s) that it is not a burden on the Examiner to search SEQ ID NO: 1-3, 5-6, 8-10. This is not found persuasive because the inventions are distinct as noted in the last Office Action, as shown by the distinctness described therein. Furthermore, , a search is directed to references which would render the invention obvious, as well as references directed to anticipation of the invention, and therefore requires a search of relevant literature in many different areas of subject matter. Claims 57-61, 66, 72, 74-76, 78, 80 read on the elected Group. Claims 62-65, 67-71, 73, 77, 79 are withdrawn from further consideration pursuant to 37 CFR 1.142(b).

The requirement is still deemed proper and is therefore made FINAL.

### ***Claim Objections***

Claims 57, 60, 61 are objected to because of the following informalities: They contain subject matter directed to non-elected Groups. Appropriate correction is required.

Claim 57 is objected to because of the following informalities: It does not end in a period. See MPEP 608.01(m).

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 57-61, 66, 72, 74-76, 78, 80 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The method recited in the claims do not

Art Unit: 1646

require the hand of man. The claims read on a process which occurs in nature, i.e. the production of a protein of SEQ ID NO: 9.

***Claim Rejections - 35 USC § 112 first paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 57-61, 66, 72, 74-76, 78, 80 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of producing a protein encoded by the nucleic acid of SEQ ID NO: 9, does not reasonably provide enablement for a method of producing a protein which is a fragment of the protein encoded by SEQ ID NO: 9, or encoded by a nucleic acid which hybridizes to SEQ ID NO: 9. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Claims 57-61, 66, 72, 74-76, 78, 80 are overly broad since insufficient guidance is provided as to which of the myriad of encoded polypeptide species encompassed by the claim will retain the characteristics of the protein encoded by SEQ ID NO: 9. Applicants do not disclose any actual or prophetic examples on expected performance parameters of any of the possible muteins of the protein encoded by SEQ ID NO: 9. It is known in the art that even single amino acid changes or differences in the amino acid sequence of a protein can have dramatic effects on the protein's function. It is also known in the art that a single amino acid change in a protein's sequence can drastically affect the structure of the protein and the architecture of an entire cell. For example, Voet et al. (1990) teaches that a single Glu to Val substitution in the

Art Unit: 1646

beta subunit of hemoglobin causes the hemoglobin molecules to associate with one another in such a manner that, in homozygous individuals, erythrocytes are altered from their normal discoid shape and assume the sickle shape characteristic of sickle-cell anemia, causing hemolytic anemia and blood flow blockages (pages 126-128, section 6-3A and page 230, column 2, first paragraph).

Since the claims encompass many polypeptide species, and given the art recognized unpredictability of the effect of mutations on protein function, it would require undue experimentation to practice the claimed method. See *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404. The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. The factors considered to be relevant in the instant case are set forth below:

(1) the breadth of the claims - The claims are drawn to a method of producing a protein which is a fragment of the protein encoded by SEQ ID NO: 9, or encoded by a nucleic acid which hybridizes to SEQ ID NO: 9.

(2) the nature of the invention - The instant invention is a method of producing a protein which is a fragment of the protein encoded by SEQ ID NO: 9, or encoded by a nucleic acid which hybridizes to SEQ ID NO: 9.

(3) the state of the prior art - The Voet reference demonstrates that even single amino acid changes or differences in the amino acid sequence of a protein can have dramatic effects on the protein's function.

(5) the level of predictability in the art - The Voet reference demonstrates the unpredictability of the protein art.

Art Unit: 1646

(6) the amount of direction provided by the inventor - Applicant has only taught a method of producing a protein encoded by the nucleic acid of SEQ ID NO: 9, not a method of producing a protein which is a fragment of the protein encoded by SEQ ID NO: 9, or encoded by a nucleic acid which hybridizes to SEQ ID NO: 9.

(7) the existence of working examples - Working examples are provided only for taught a method of producing a protein encoded by the nucleic acid of SEQ ID NO: 9.

(8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. Given the breadth of claims 57-61, 66, 72, 74-76, 78, 80 in light of the predictability of the art as determined by the number of working examples, the level of skill of the artisan, and the guidance provided in the instant specification and the prior art of record, it would require undue experimentation for one of ordinary skill in the art to practice the claimed invention.

Claims 57-61, 66, 72, 74-76, 78, 80 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Art Unit: 1646

These are genus claims. The claims encompass many polypeptide species which are encoded by fragments of SEQ ID NO: 9, or encoded by nucleic acids which hybridize to SEQ ID NO: 9 without indicating what distinguishing attributes are shared by the members of the genus. The specification and claim do not place any limit on the number of amino acid substitutions, deletions, insertions and/or additions that may be made to the protein encoded by SEQ ID NO: 9. Thus, the scope of the claim includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Although the specification states that these types of changes are routinely done in the art, the specification and claim do not provide any guidance as to what changes should be made. Structural features that could distinguish compounds in the genus from others in the protein class are missing from the disclosure. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, the polypeptide encoded by SEQ ID NO: 9 alone is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of a method of producing a protein which is a fragment of the protein encoded by SEQ ID NO: 9, or encoded by a nucleic acid which hybridizes to SEQ ID NO: 9.

Art Unit: 1646

***Claim Rejections - 35 USC § 112 second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 57-61, 66, 72, 74-76, 78, 80 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 57 is vague and indefinite because it is incomplete, and it is unclear what functional limitation is intended for the polypeptide produced by the claimed method. Claims 58-61, 66, 72, 74-76, 78, 80 are rejected insofar as they depend on claim 57.

Claim 57 recites the term "stringent conditions", which is a conditional term and renders the claim indefinite. Furthermore, some nucleic acids which might hybridize under conditions of moderate stringency, for example, would fail to hybridize under conditions of high stringency. The metes and bounds of the claim thus cannot be ascertained. This rejection could be obviated by supplying specific conditions supported by the specification which Applicant considers to be "stringent". Claims 58-61, 66, 72, 74-76, 78, 80 are rejected insofar as they depend on the recitation in claim 57 of "stringent conditions".

***Conclusion***

No claim is allowed.



Art Unit: 1646

*Advisory Information*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F. Murphy whose telephone number is 703-305-7245.


The examiner can normally be reached on M-F 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 703-308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Joseph F. Murphy, Ph. D.  
Patent Examiner  
Art Unit 1646  
August 6, 2002

  
**DAVID S. ROMEO**  
**PRIMARY EXAMINER**